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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/539,950 | 06/17/2005 | Bernard Roald Bohmer | PRO-015 | 6813 |
| 28661 7590 05/07/2007 SIERRA PATENT GROUP, LTD. 1657 Hwy 395, Suite 202 Minden, NV 89423 | | | | |
| | | | EXAMINER DOWE, KATHERINE MARIE | |
| | | | ART UNIT 3734 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,950

Applicant(s)

BOHMER, BERNARD ROALD

Examiner

Katherine M. Dowe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-33 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/17/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response to the preliminary amendment filed 6/17/2005. In particular, claims 1-10 have been cancelled and claims 11-33 have been added. Thus, claims 11-33 are currently pending.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

3. The disclosure is objected to because of the following informalities: There are no headings throughout the specification. Please see the suggested headings below to make the specification more clear.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.

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- (1) Field of the Invention.
- (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Appropriate correction is required.

Claim Objections

4. Claim 11 is objected to because of the following informalities: Claim 11 states "the flow channel has a minimum diameter of less than 1mm. By giving a minimum diameter, it is implied the Applicant is setting up a range for the flow channel diameter, however no maximum diameter is given. Please clarify the claim by claiming a single preferred diameter or by setting up a complete range for the diameter values. Currently, Examiner is interpreting the claim to read that at least one portion of the flow channel must be less than 1 mm in diameter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 recites the limitation "the cartridge" in line 9 of the claim. However, the cartridge is not positively claimed earlier in the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claims 11, 18-20, and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 11 never positively claims a cartridge, thus the device must merely be *capable* of "receiving a single use cartridge". Thus, limitations placed on a cartridge do not hold patentable weight.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. Claims 11-16 and 21-29, are rejected under 35 U.S.C. 103(a) as being unpatentable over Mailot et al. (US 5,127,903) in view of Van Der Merwe (US 5,843,030). Regarding claims 11, 13, 21, Mailot et al. disclose the invention substantially as claimed including a pacifier capable of receiving a single use cartridge (10) comprising a base having a cartridge chamber (8), a nipple (2), a plurality of parallel flow channels (20) between the cartridge and the nipple, a hole (28) in communication with the flow channel in the nipple, and a cap at an insertion opening to the cartridge chamber as shown below in Fig 1:

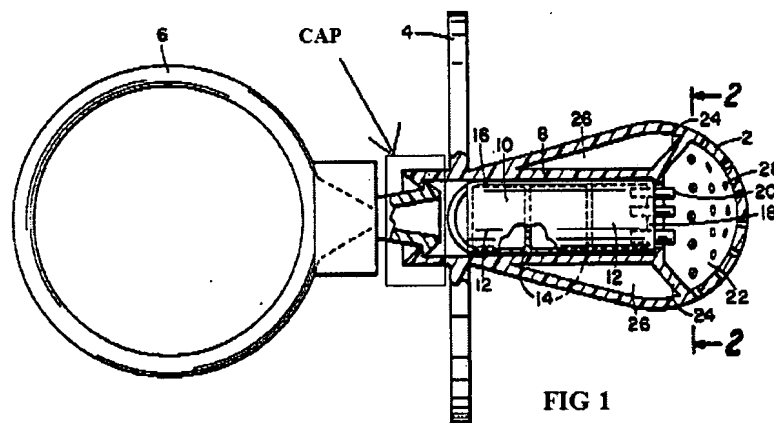


FIG 1

Furthermore, the proximal ends of the capillary tubes forming the flow channels may be capable of piercing a pierceable sheet of a cartridge. However, Mailot et al. is silent on the diameter of the flow channel. Van Der Merwe discloses a similar pacifier (1) for delivering a liquid comprising a chamber (15) in communication with a flow channel (8), which extends through a nipple (1). Van Der Merwe teaches the flow channel has an internal diameter of 0.25 to 1 mm (col 6, ln 56-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the device of Mailot et al. such that the minimum diameter of the flow channel is less than 1mm such that the administration of the fluid will be controlled by keeping the flow communication between the chamber and the outlet to a minimum volume.

Regarding claim 12, Mailot et al. disclose the flow channel (20) extends along almost the entire length of the nipple since there is only a small distance between the end of the capillary tube (20) and the outlet holes (22) on the nipple surface (Fig 1).

Regarding claims 14, 22, and 23, Mailot et al. disclose an enlargement of the flow channel (22), or pre-chamber, is formed at the hole.

Regarding claims 15, 24, and 25, Mailot et al. disclose the cartridge chamber (8) extends partly into the nipple (2) (Fig 1).

Regarding claims 16 and 26-29, Mailot et al. do not disclose the cap is a hinged cap. However, Van Der Merwe teaches the chamber cap (51) is connected by a hinge (57) such that the cap may pivot about the hinge between an open position (Fig 1b) where fluid may be introduced through a syringe (17) and a closed position (Fig 1a). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Mailot et al. such that the cap was connected by a hinge. Thus, the cap could easily be pivoted to an open position to insert a cartridge in the cartridge chamber without completely removing the cap and risk contaminating the cap surface in contact with the cartridge, which may occur if the cap is laid down once removed.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mailot et al. (US 5,127,903) and Van Der Merwe (US 5,843,030), as applied to claim 16 above, further in view of Urban (US 4,078,566). Regarding claims 11, 13, 21, Mailot et al. disclose the invention substantially as claimed including a pacifier capable of receiving a single use cartridge (10) comprising a base having a cartridge chamber (8), a nipple (2), a plurality of parallel flow channels (20) between the cartridge and the nipple, a hole (28) in communication with the flow channel in the nipple, and a cap at an insertion opening to the cartridge chamber as shown above in Fig 1. Furthermore, the proximal ends of the capillary tubes forming the flow channels may be capable of piercing a pierceable sheet of a cartridge. However, Mailot et al. is silent on the diameter of the flow channel. Van Der Merwe discloses a similar pacifier (1) for delivering a liquid comprising a chamber (15) in communication with a flow channel (8), which extends through a nipple (1). Van Der Merwe teaches the flow channel has an internal diameter of 0.25 to 1 mm (col 6, ln 56-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Mailot et al. such that the minimum diameter of the flow channel is less than 1mm such that the administration of the fluid will be controlled by keeping the flow communication between the chamber and the outlet to a minimum volume.

Furthermore, Mailot et al. do not disclose the cap is equipped with an air inlet hole. Urban discloses a similar pacifier device for delivering a liquid comprising a cavity (15) in a nipple member (1), which dispenses liquid through an outflow opening (10). Urban teaches a second hole is formed in the cap (2) to help facilitate the flow of liquid

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from the air-tight chamber (15) by preventing a vacuum from forming in the chamber (col 3, ln 41-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Mailot et al. such that the cap had an air inlet hole to prevent a vacuum from forming in the chamber and thus ensuring there is sufficient fluid flow through the flow channels.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miller et al. (5,123,915) additionally disclose a pacifier for receiving a single use cartridge in which the cartridge is pierced when the cap is secured to allow the fluid to flow from the cartridge to the nipple through a flow channel.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
April 25, 2007



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER